

FORM PTO-1449
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.

SERIAL NO.

SRL 6067

09/023,401

LIST OF PRIOR ART CITED BY APPLICANT

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APPLICANT

Gary S. Jacob

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2-12-98

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1614

U.S. PATENT DOCUMENTS

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EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	27	3,590,028	6/1971	Arcamone	260	210	TECH CENTER 1600/2900
	28	4,012,448	3/1977	Smith et al.	260	591	
	29	4,065,562	12/1977	Ohata et al.	424	267	
	30	4,182,767	1/1980	Murai et al.	424	267	
	31	4,260,622	4/1981	Junge et al.	424	267	
	32	4,327,725	5/1982	Cortese et al.	128	260	
	33	4,524,060	6/1985	Mughal et al.	424	19	
	34	4,533,668	8/1985	Matsumura et al.	514	321	
	35	4,611,058	9/1986	Koebernick	546	242	
	36	4,612,008	9/1986	Wong et al.	604	892	
	37	4,765,989	8/1988	Wong et al.	424	473	
	38	4,783,337	11/1988	Wong et al.	424	468	
	39	4,806,650	2/1989	Schröder et al.	546	242	
b	40	4,849,430	7/1989	Fleet et al.	514	315	
	41	4,880,830	11/1989	Rhodes	424	470	
	42	4,957,926	9/1990	Jacob et al.	514	315	
p	43	5,003,072	3/1991	Partis et al.	546	243	
	44	5,011,829	4/1991	Hirsch et al.	514	50	
	45	5,030,638	7/1991	Partis et al.	514	315	
	46	5,041,441	8/1991	Radin et al.	514	237.8	
	47	5,068,112	11/1991	Samejima et al.	424	495	
	48	5,190,765	3/1993	Jao et al.	424	473	
5	49	5,144,037	9/1992	Partis et al.	546	116	

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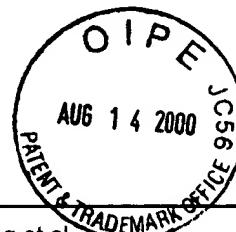
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	50	5,151,519	9/1992	Behling et al.	546	219	
	51	5,281,724	1/1994	Behling et al.	549	334	
	52	5,310,745	5/1994	Partis et al.	514	315	
	53	5,331,096	7/1994	Koszyk et al.	546	115	
	54	5,411,970	5/1995	Partis et al.	514	315	
	55	5,451,679	9/1995	Barta et al.	546	219	
	56	5,472,969	12/1995	Platt et al.	514	315	
	57	5,491,135	2/1996	Blough	514	115	
	58	5,525,616	6/1996	Platt et al.	514	315	
	59	5,536,732	7/1996	Lesur et al.	514	317	
	60	5,595,981	1/1997	Barta et al.	514	63	
	61	5,612,480	3/1997	Barta et al.	544	180	
	62	5,663,342	9/1997	Barta et al.	546	6	

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
63		2,020,278	3/1979	U.K.	C07D	211/40		
64		0 324 328	7/1989	EPO	A61K	31/445		
65		0 350 012	1/1990	EPO	A61K	31/445		
66		0 367 748	5/1990	EPO	C07D	211/46		
67		0 449 026	10/1991	EPO	C07D	491/04		
68		0 494 850	7/1992	EPO	C07D	211/46		
69		0 566 556	10/1993	EPO	C07D	211/40		
70		WO87/03903	7/1987	PCT	C12N	05/00		
71		WO95/22975	8/1995	PCT	A61K	31/445		
72		WO96/40110	12/1996	PCT	A61K	31/35		

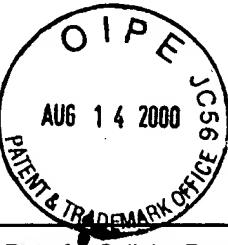
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					SRL 6067	09/023,401			
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)					 <p>AUG 14 2000</p>				
	73.	WO97/00881	1/1997	PCT	C07H	17/02		No	
	74.	WO98/35685	8/1998	PCT	A61K	31/70			
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)									
	75.	Dalton, et al., "A Phase II Randomized Study of Oral Verapamil as a Chemosensitizer to Reverse Drug Resistance in Patients with Refractory Myeloma," February 1, 1995, Cancer, Vol. 75, No. 3, pp. 815-820							
	76.	Jacob et al., "Aminosugar Attenuation of HIV Infection," 1992, Natural Products as Antiviral Agents, pp. 137-152							
	77.	Karpas, et al., "Aminosugar Derivatives as Potential Anti-Human Immunodeficiency Virus Agents," December, 1988, Proc. Natl. Acad. Sci., Vol. 85, pp. 9229-9233							
	78.	Welsh, et al., "Accumulation of Fatty-Alcohol in MCF-7 Breast Cancer Cells," November 15, 1994, Archives of Biochemistry and Biophysics, Vol. 315, No. 1, pp. 41-47							
	79.	Lavie, et al., "Agents that Reverse Multidrug Resistance, Tamoxifen, Verapamil, and Cyclosporin A, Block Glycosphingolipid Metabolism by Inhibiting Ceramide Glycosylation in Human Cancer Cells," August 20, 1996, The Journal of Biological Chemistry, Vol. 272, No. 3, pp. 1682-1687							
	80.	Lavie, et al., "Accumulation of Glucosylceramides in Multidrug-Resistant Cancer Cells," August 9, 1996, The Journal of Biological Chemistry, Vo. 271, No. 32, pp. 19530-19536							
	81.	Inokuchi, et al., "Antitumor Activity Via Inhibition of Glycosphingolipid Biosynthesis," September 3, 1987, Cancer Letters, Vol. 38, pp. 23-30							
	82.	Holleran, et al., "Characterization of Cellular Lipids in Doxorubicin-Sensitive and -Resistant P388 Mouse Leukemia Cells," 1986, Cancer Chemother Pharmacol, 17:11-15							
	83.	Fisher, et al., "Clinical Studies with Modulators of Multidrug Resistance," April 1995, Drug Resistance in Clinical Oncology and Hematology, Vol. 9, No. 2, pp. 363-382							
	84.	Raderer, et al., "Clinical Trials of Agents that Reverse Multidrug Resistance," December 15, 1993, Cancer, Vol. 72, No. 12, pp. 3553-3563							
	85.	Tan, et al., "Chemical Modification of the Glucosidase Inhibitor 1-Deoxyojirimycin," August 5, 1991, The Journal of Biological Chemistry, Vo. 266, No. 22, pp. 14504-14510							
	86.	Wang, et al., "Chemo-enzymatic Synthesis of Five-membered Azasugars as Inhibitors of Fucosidase and Fucosyltransferase: An Issue Regarding The Stereochemistry Discrimination at Transition States," 1993, Tetrahedron Letters, Vol. 34, No. 3, pp. 403-406							
	87.	Jezowska-Bojczuk, et al., "Copper(II) Interactions with an Experimental Antiviral Agent, 1-Deoxyojirimycin, and Oxygen Activation by Resulting Complexes," 1996, Journal of Inorganic Biochemistry, Vol. 64, pp. 231-246							
	88.	Ramu, et al., "Differences in Lipid Composition of Doxorubicin-Sensitive and -Resistant P388 Cells," April 1984, Cancer Treatment Reports, Vol. 68, No. 4, pp. 637-641							

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LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)			APPLICANT Gary S. Jac b	
			FILING DATE 2-12-98	GROUP 1614
	89	Beketic-Oreskovic, et al., "Decreased Mutation Rate for Cellular Resistance to Doxorubicin and Suppression of mdr1 Gene Activation by the Cyclosporin PSC 833," November 1, 1995, Journal of the National Cancer Institute, Vol. 87, No. 21, pp. 1593-1602		
	90	Volm, et al., "Expression of Resistance Factors (P-Glycoprotein, Glutathione S-Transferase-II, and Topoisomerase II) and Their Interrelationship to Proto-Oncogene Products in Renal Cell Carcinomas," June 15, 1993, Cancer, Vol. 71, No. 12, pp. 3981-3987		
	91	Lu, et al., "Evidence That N-Linked Glycosylation is Necessary for Hepatitis B Virus Secretion," November 10, 1995, Virology, Vol. 213, No. 2, pp. 660-665		
	92	Legler, et al., "Glycosylceramidase from Calf Spleen: Characterization of its Active Site with 4-n-Alkylurnbelliferyl β-glucoside and N-alkyl Derivatives of 1-Deoxynojirimycin," December 1985, Bio-Chem Hoppe-Seyler, Vol. 366, pp. 1113-1122		
	93	Hardman, et al., "Goodman & Gilman's The Pharmacological Basis of Therapeutics," 1996, McGraw-Hill, Ninth Edition, Chapter 32: Drugs Used for the Treatment of Myocardial Ischemia, Verapamil, pp. 767-774, 780-781, 799-801, and 829		
	94	Mehta, et al., "Hepatitis B Virus (HBV) Envelope Glycoproteins Vary Drastically in Their Sensitivity to Glycan Processing: Evidence that Alteration of a Single N-Linked Glycosylation Site Can Regulate HBV Secretion," March 1997, Proc. Natl. Acad. Sci., Vol. 94, pp. 1822-1827		
	95	Hollinger, "Hepatitis B Virus," Field Virology, Third Edition, Chapter 86, pp. 2739-2807		
	96	Fleet, et al., "Inhibition of HIV Replication by Amino-Sugar Derivatives," September 1988, Federation of European Biochemical Societies, Vol. 237, No. 1,2, pp. 128-132		
	97	Newbrun, et al., "Inhibition by Acarbose, Nogirimycin and 1-Deoxynojirimycin of Glucosyltransferase Produced by Oral Streptococci," 1983, Archs Oral Biol., Vol. 28, No. 6, pp. 531-536		
	98	Saunier, et al., "Inhibition of N-Linked Complex Oligosaccharide Formation by 1-Deoxynojirimycin, An Inhibitor of Processing Glucosidases," December 10, 1982, The Journal of Biological Chemistry, Vol. 257, No. 23, pp. 14155-14161		
	99	Abe, et al., "Induction of Glucosylceramide Synthase by Synthase Inhibitors and Ceramide," 1996, Biochimica et Biophysica Acta, Vol. 1299, pp. 333-341		
	100	Abe, et al., "Improved Inhibitors of Glucosylceramide Synthase," 1992, J. Biochem., Vol. 111, pp. 191-196		
	101	Elbein, "Inhibitors of the Biosynthesis and Processing of N-Linked Oligosaccharide Chains," 1987, Ann. Rev. Biochem., 56:497-534		
	102	Radin, et al., "Inhibitors of Cerebroside Metabolism," 1981, Methods in Enzymology, Vol. 72, pp. 673-684		
	103	Prence, et al., "In Vitro Accumulation of Glucocerebroside in Neuroblastoma Cells: A Model for Study of Gaucher Disease Pathobiology," 1996, Journal of Neuroscience Research, 43:365-371		

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 <p style="text-align: center;">O I P E AUG 14 2000 PATENT & TRADEMARK OFFICE WASH. D.C.</p>				
			FILING DATE 2-12-98	GROUP 1614
104	Bradley, et al., "Mechanism of Multidrug Resistance," 1988, <i>Biochimica et Biophysica Acta</i> , Vol. 948, pp. 87-128			
105	Mulder, et al., "Multidrug Resistance-Modifying Components in Human Plasma with Potential Clinical Significance," January 1996, <i>Journal of Experimental Therapeutics & Oncology</i> , Vol. 1, No. 1, pp. 13-22			
106	Ardalan, et al., "Mechanism of Action of a New Antitumor Agent, Carbetimer," November 1986, <i>Cancer Research</i> , Vol. 46, pp. 5473-5476			
107	Platt, et al., "Modulation of Cell-Surface Transferrin Receptor by the Imino Sugar N-butyldeoxynojirimycin," 1992, <i>Eur. J. Biochem.</i> , Vol. 208, pp 187-193			
108	Kawakami, et al., "Monoclonal Antibodies with Affinity to Self-Complementary Left-Handed DNA Containing Cyclonucleosides with High Anti Conformation," 1994, <i>Nucleosides & Nucleotides</i> , Vol. 13(1-3), pp. 421-427			
109	Dicato, et al., "Multidrug-Resistance: Molecular and Clinical Aspects," 1997, <i>Cytokines, Cellular & Molecular Therapy</i> , Vol. 3, No. 2, pp. 91-100			
110	Bolhuis, et al., "Mechanisms of Multidrug Transporters," 1997, <i>FEMS Microbiology Reviews</i> , Vol. 21, pp. 55-84			
111	Carbohydrate Chemistry; Chapter 20: Nucleosides, undated, pp. 242-276			
112	Platt, et al., "N-Butyldeoxynojirimycin Is a Novel Inhibitor of Glycolipid Biosynthesis," March 18, 1994, <i>The Journal of Biological Chemistry</i> , Vol. 269, No. 11, pp. 8362-8365			
113	Platt, et al., "N-Butyldeoxygalactonojirimycin Inhibits Glycolipid Biosynthesis but Does Not Affect N-Linked Oligosaccharide Processing," October 28, 1994, <i>The Journal of Biological Chemistry</i> , Vol. 269, No. 43, pp. 27108-27114			
114	Platt, et al., "New Approach for the Treatment of Gauchers Disease," March 1996, <i>Gauchers Association Newsletter</i> , one page			
115	Wilson, et al., "Nitrogen Glycosylation Reactions Involving Pyrimidine and Purine Nucleoside Bases with Furanoside Sugars," December 1995, <i>Synthesis</i> , Department of Chemistry, Emory University, pp. 1465-1479			
116	Kers, et al., "Nucleoside Phosphonates: Development of Synthetic Methods and Reagents," 1996, <i>Nucleosides & Nucleotides</i> , 15(1-3), pp. 361-378			
117	Tsuruo, et al., "Overcoming of Vincristine Resistance in R388 Leukemis In Vivo and In Vitro Enhanced Cytotoxicity of Vincristine and Vinblastine by Verapamil," May 1981, <i>Cancer Research</i> , Vol. 41, pp. 1967-1972			
118	Wright, et al., "Phospholipid and Ether Linked Phospholipid Content Alter with Cellular Resistance to Vinblastine," December 17, 1985, <i>Biochemical and Biophysical Research Communications</i> , Vol. 133, No. 2, pp. 539-545			
119	Bradley, et al., "P-glycoprotein, Multidrug-Resistance and Tumor Progression," 1994, <i>Cancer and Metastasis Reviews</i> , Vol. 13, pp. 223-233			
120	May, et al., "Plasma Membrane Lipid Composition of Vinblastine Sensitive and Resistant Human Leukaemic Lymphoblasts," 1988, <i>Int. J. Cancer</i> , Vol. 42, pp. 728-733			

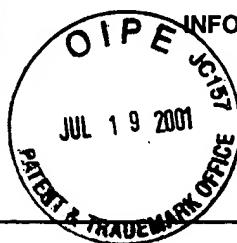
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		APPLICANT Gary S. Jacob	FILING DATE 2-12-98	GROUP 1614	
121	Platt, et al., "Prevention of Lysosomal Storage in Tay-Sachs Mice Treated with N-Butyldeoxynojirimycin," April 18, 1997, Science, Vol. 276, pp. 428-431				
122	Wishart, et al., "Quinidine as a Resistance Modulator of Epirubicin in Advanced Breast Cancer: Mature Results of a Placebo-Controlled Randomized Trial," September 1994, Journal of Clinical Oncology, Vol. 12, No. 9, pp. 1771-1777				
123	Chabner, et al., "Reversal of Multidrug Resistance," January 1991, Journal of Clinical Oncology, Vol. 9, No. 1, pp. 4-6				
124	Hui, et al., "Reduced p21 ^{WAF1/CIP1} Expression and p53 Mutation in Hepatocellular Carcinomas," March 1997, Hepatology, Vol. 25, No. 3, pp. 575-579				
125	Radin, "Rationales for Cancer Chemotherapy with PDMP, a Specific Inhibitor of Glucosylceramide Synthase," 1994, Molecular and Chemical Neuropathology, Vol. 21, pp. 111-127				
126	Arends, "Recueil des Travaux Chimiques des Pays-Bas," Journal of the Royal Netherlands Chemical Society, February 1994, Recl. Trav. Chim. Pays-Bas 113, 63-114, contents page only				
127	Shukla, et al., "Rapid Kidney Changes Resulting from Glycosphingolipid Depletion by Treatment with a Glucosyltransferase Inhibitor," 1991, Biochimica et Biophysica Acta, Vol. 1083, pp. 101-108				
128	Block, et al., "Secretion of Human Hepatitis-B Virus is Inhibited by the Imino Sugar N-butyldeoxynojirimycin," March 1994, Proc. Natl. Acad. Sci., Vol. 91, pp. 2235-2239				
129	Inokuchi, et al., "Stimulation of Glycosphingolipid Biosynthesis by L-Threo-1-Phenyl-2-Decanoylamino-1-Propanal and Its Homologs in B16 Melanoma Cells," 1995, J. Biochem., Vol. 117, No. 4, pp. 766-773				
130	Abe, et al., "Structural and Stereochemical Studies of Potent Inhibitors of Glucosylceramide Synthase and Tumor Cell Growth," 1995, Journal of Lipid Research, Vol. 36, pp. 611-621				
131	Ogawa, et al., "Synthesis of Potent β -D-Glucocerebrosidase Inhibitors: N-Alkyl- β -Valienamines," 1996, Bioorganic & Medicinal Chemistry Letters, Vol. 6, No. 8, pp. 929-932				
132	Vorbrüggen, et al., "Some Recent Trends and Progress in Nucleoside Synthesis," 1996, Acta Biochimica Polonica, Vol. 43, No. 1, pp. 25-36				
133	Sobrero, et al., "Sequential Dichloromethotrexate (DCM) and 5-Fluorouracil (FU): A Synergistic Combination Potentially Valuable for Hepatic Artery Infusion Therapy," March 1983, ASCO Abstracts, Clinical Pharmacology, Vol. 2, Article C-102, p. 26				
134	Wadkins, et al., "The Role of Drug-Lipid Interactions in the Biological Activity of Modulators of Multi-Drug Resistance," 1993, Biochimica et Biophysica Acta, Vol. 1153, pp. 225-236				
135	Doige, et al., "The Effects of Lipids and Detergents on ATPase-Active P-Glycoprotein," 1993, Biochimica et Biophysica Acta, Vol. 1146, pp. 65-72				
136	Ries, et al., "Treatment of Advanced and Refractory Breast Cancer with Doxorubicin, Vincristine and Continuous Infusion of Verapamil. A Phase I-II Clinical Trial," 1991, Med. Oncol. & Tumor Pharmacother, Vol. 8, No. 1, pp. 39-43				

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	137	Radin, et al., "Treatment of Gaucher Disease with an Enzyme Inhibitor," 1996, Glycoconjugate Journal, Vol. 13, pp. 153-157		
	138	Fischl, et al., "The Safety and Efficacy of Combination N-Butyl-Deoxynojirimycin (SC-48334) and Zidovudine in Patients with HIV-1 Infection and 20-500 CD4 Cells/mm ³ ," 1994, Journal of Acquired Immune Deficiency Syndromes, Vol. 7, pp. 139-147		
	139	Block, et al., "The Secretion of Human Hepatitis B Virus is Inhibited by the Imino Sugar, N-Butyl-Deoxynojirimycin," undated, Jefferson Cancer Institute, et al., No. 81, one page		
D	140	Mutchnick, et al., "Thymosin Treatment of Chronic Hepatitis B: A Placebo-controlled Pilot Trial," 1991, Hepatology, Vol. 14, No. 3, pp. 409-415		
	141	Simon, et al., "Treatment of Chronic Hepatitis C with Interferon Alfa-n3: A Multicenter, Randomized, Open-Label Trial," February 1997, Hepatology, Vol. 25, No. 2, pp. 445-448		
	142	Cabot, et al., "Tamoxifen Retards Glycosphingolipid Metabolism in Human Cancer Cells," 1996, FEBS Letters (17548), Vol. 394, pp. 129-131		
	143	Lindsay, et al., "Thymosin α_1 Treatment of Chronic Hepatitis B: A Multicenter, Randomized, Placebo-Controlled Double Blind Study," April 1995, AASLD, A1127, one page		
	144	Mutchnick, et al., "Thymosin Treatment of Chronic Active Hepatitis B (CAHB): A Preliminary Report on a Controlled, Double Blind Study," 1988, Hepatology, Vol. 8, No. 5, Article 208, p. 1270		
D	145	Dwek, Raymond, "Glycobiology: Toward Understanding the Function of Sugars," Chem. Rev. 1996, 96, pp. 683-720		
D	146	Platt, Frances M., et al., "Inhibitors of Glycosphingolipid Biosynthesis," Trends in Glycoscience and Glycotechnology, Vol. 7, No. 38, November 1995, pp. 495-511		

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INFORMATION DISCLOSURE STATEMENT
BY APPLICANT(S)
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Sheet 1 of 3

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U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
D	147	4,269,857	5/1981	Tokuda et al.	424	325	
D	148	5,221,746	6/1993	Partis et al.	546	220	
149	5,264,356	11/1993	Rohrschneider	435	236		
150	5,622,972	4/1997	Bryant et al.	514	315		
151	5,703,058	12/1997	Schinazi et al.	514	45		
152	6,093,702	7/2000	Malley et al.	514	45		

FOREIGN PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
153	2,700,267	1/1993	FR		A61K	9/107		
154	0,401,194	6/1990	EPO		A61K	31/70		
155	0,477,160	9/1991	EPO		C12P	17/04		
156	0,691,327	3/1994	EPO		C07C	217/28		
157	0,729,747	2/1996	EPO		A61K	7/48		
158	WO91/17145	11/1991	PCT		C07D	211/46		
159	WO94/04546	3/1994	PCT		C07H	17/02		Abstract
160	WO95/06061	3/1995	PCT		C07K	5/03		
161	WO99/29321	6/1999	PCT		A61K	31/445		
162	WO99/40916	8/1999	PCT		A61K	31/445		

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

163	Acosta, et al., "Agents for Treating Human Immunodeficiency Virus Infection," Am. J. Hosp. Pharm., Vol. 51, September 15, 1994, pp. 2251-2287
164	Tennant, et al., "Animal Models in the Preclinical Assessment of Therapy for Viral Hepatitis," Antiviral Therapy, Vol. 1, (Suppl. 4), 1996, pp. 47-52

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Sheet 2 of 3

APPLICANT
Gary S. Jacob et al.FILING DATE
February 12, 1998GROUP
1614
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